REMARKS

Reconsideration of this application is respectfully requested in view of the foregoing amendments and discussion presented herein.

1. Restriction Requirement.

In responding to the prior Office Action, the Applicant met the restriction requirement by electing "invention I" recited in claims 1-8. That election, without traverse, is confirmed herewith.

As a result of that election Claims 9 - 35 were withdrawn from consideration, including 17 claims including 3 independent claims. With the immediate Amendment Applicant herein cancels those claims (Claims 9 - 35) only for the purpose of reducing claim fees in view of the new claims incorporated herein, which replace those claims but are drawn to the elected invention of claim 1.

Cancellation of claims 9 - 35 being executed without prejudice, disclaimer, waiver or estoppel, and Applicant retains the right to pursue the subject matter thereof in future related patent applications, such as through the filing of a divisional application or continuation.

2. Amendment of Drawings.

The drawings have been amended to correct errors in FIG. 5 which were detected when preparing this response.

In the flowchart of FIG. 5 blocks 104, 106 within packetizing system 98 were mislabeled. These blocks have been corrected to read as follows: block 104 "Collect

Individualized Doses" and block 106 "Package Set of Doses". Support for this is found in the sketch within the provisional application (copy of which is attached) and in the portion of the specification commencing on page 23, lines 3-11:

> "A block diagram of the major functions within the packetizing system are shown in block 98, as an order is triggered at block 100 for fulfillment. It will be appreciated that the time for fulfilling the order is preferably determined by the date and time that the first individualized dose packet within the order are to be taken; modified of course by user settings as to lead time. The order is then pulled up at block 102 and preferably verified before fulfillment is allowed. The individualized doses are then collected at block 104 and the collection is packaged 106 within individualized packets, or containers, whereupon the order is boxed and shipped to the consumer at block 108."

It should be noted that the reference to block 106 was inadvertently omitted from the specification, and has been corrected, in a current amendment to the specification.

3. Amendment of Specification.

The Applicant has amended the specification to correct typographical errors discovered while preparing this response, and apologizes for any inconvenience which this may have caused the Examiner.

A missing reference number 106 referring to "Package Set of Doses" was inserted in the text where it refers to packaging. The line being changed as follows:

> "The individualized doses are then collected at block 104 and the collection is packaged 106 within individualized packets, or containers, whereupon the order is boxed and shipped to the consumer at block 108."

The amendment is supported by the specification and preceding provisional application and does not add new matter to the case.

4. Rejection of Claims 1-8 under 35 U.S.C. §102(b).

Claims 1 - 8 have been rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Yuyama et al. (U.S. Patent 5,946,883) as submitted as a reference by Applicant.

After carefully considering the grounds for the rejection the applicant responds as follows.

Applicant respectfully submits that Yuyama et al. '883 reference has been misapplied to claims 1-8. Support for the rejection of claims 1-8 suffers from a number of shortcomings. Yuyama et al. '883 does not teach the elements of Applicant's invention as recited in the claims. Furthermore, aspects of many of the dependent claims within the application have not been given any separate consideration whatsoever. Problems with the rejection are now described with regard to specific claims and elements therein.

Claim 1. This is the independent claim within this group of claims 1-8. In support of this anticipation rejection generalized aspects taught by Yuyama et al. '883 have been described. However, not all aspects of Claim 1 have been considered in relation to the reference.

Reference does not show all subject matter of claim

The relied upon reference of Yuyama et al. '883 does not describe packetizing a series of individualized doses from a dose schedule, which is apparent in Claim 1. Specifically, the applicants claim is drawn to packetizing a scheduled series of doses, the understanding of which is further brought out later in Claim1: *"an interface*

associated with said computer wherethrough a dosing schedule is specified ...which is communicated to said packetizing system for packaging said series of doses."

These important aspects of Applicant's invention, which are brought out throughout the specification and even reflected in the title *"System and Method for Providing Temporal Patient Dosing"* are not taught by the Yuyama et al. '883 reference. The importance of these aspects being recited throughout the application, such as in the first line of the abstract which reads: *"A system and method for creating a series of individualized custom doses for a consumer."* Another aspect of this is also recited in the abstract: *"...each individualized custom dose, comprising a plurality of medications and/or supplements, is individually separable from the remaining doses within the series."*

By contrast, Yuyama et al. '883 does not even teach an interface, and specifically provides no teaching whatsoever in regard to *"packaging a series of individualized doses"* according to *"dosing schedules"*.

Yuyama et al. '883 is directed at "An Apparatus for Collecting Ampoules", having the goal of providing a list that can be easily highlighted of the ampoules which are not in the automated ampoule dispenser, as described by the Abstract of Yuyama et al. '883.

Furthermore, Yuyama et al. does not operate with regard to "pills", but ampoules. The entire description by Yuyama et al., except for a single line suggestion at col. 3, line 41, refers to collecting "ampoules". All the claims of Yuyama are similarly specifically directed at collecting "ampoules". Still further there is no description of "packetizing" the injection ampules, (which would be absurd), as the term "packetizing" is recited in

applicant's specification or plainly understood for creating the series of individualized dose packets for the recipient, not a holding tray.

Reference Lack Physical Identity with Claimed Invention

It is a well established principle that all claim elements must be identically taught or inherent in a reference to support anticipation under section 102. This is mandated by the MPEP (§706.02a):

"...to support an anticipation rejection, every claim element must be taught or inherent in a single prior art reference".

This principle is further reiterated by MPEP 2131, which states:

"identical invention must be shown..."

Therefore, Yuyama et al. '883 for a number of demonstrated reasons does not constitute an anticipatory reference, and has been incorrectly applied against the Claim 1 of the immediate application.

Since Claim 1 recites subject matter not found in the cited reference it is not anticipated by that reference. There is a complete lack of identity as required of an anticipation rejection, wherein there exists only similarities. It appears to the Applicant that the similarities between the application and the Yuyama reference are even less pronounced than the similarities between Yuyama at al. '883 and a number of the prior art referenced by the Applicant via the IDS statement.

However, in order to further clarify these important aspects of the invention, the Applicant has amended Claim 1 to bring out the "scheduled series of doses" aspects with more clarity, by including that terminology in the preamble and in relation to the target of the packetizing system. It should be appreciated that these very minor

amendments in no way necessitate or can be considered grounds for requiring additional searching by the Examiner.

Claims 2 - 8. These claims depend from Claim 1, and therefore should be considered *a fortiori* allowable based on the demonstrated patentability of Claim 1.

Applicant must respectfully point out that **none of the limitations recited within these dependent claims have been given any consideration whatsoever**, which is of course contrary to all known examination practice. This situation especially dismays the Applicant, who is a sole inventor/applicant, as he would have otherwise already received an allowance on at least some claims allowing the inventor to market the invention while continuing to work with the Examiner regarding the remaining claims.

The dependent claims recite on their own merits aspects of the invention not taught by Yuyama et al., and in the following cases these are glaring oversights.

Claim 2. This claim describes packaging a series of pill doses for use by the consumer, which also inherently brings with it that the packets are sealed and marked accordingly. None of which are taught by Yuyama et al. '883.

Claim 4. This claim describes the interface of Claim 1 comprising a "web site hosted on the Internet". Clearly Yuyama et al. '883 teaches no such web interface.

Claim 6. This claim describes the computer interface which includes "an interaction/contraindication checking routine being executed on said computer system which checks said supplements and/or medications being entered into said schedule for possible interactions and contraindications with medical conditions and generates alerts in response thereto". Again - none of these aspects are taught by Yuyama et al.

'883.

Claim 7. This claim describes in detail that the interface is adapted to execute a purchase transaction, another aspect wholly absent from the Yuyama et al. '883 reference.

Claim 8. This claim describes an interface which is adapted to receive a plurality of dosing schedules from an institution for patients under their care. Again, this is very clearly not taught within the reference.

Therefore, it has been demonstrated that Claim 1 recites elements which are not found in the relied-upon reference, and it therefore not anticipated by the relied upon reference. Support for an anticipation rejection requiring that there must be no difference between the claimed invention and the reference disclosure.

Applicant respectfully requests that the rejection of Claim 1, and all claims that depend therefrom be immediately withdrawn and the instant application passed to allowance.

5. Claims are NonObvious.

Nor would the subject matter of Claims 1- 8 be obvious to a person having ordinary skill in the art in view of the cited reference. Applicant's claims recite numerous aspects with are not taught or suggested within Yuyama et al. '883, and for which no motivation or incentive could be found therein for modification toward Applicant's claimed invention. A valid *prima facie* case of obviousness, as outlined in MPEP 2143 could not be supported.

Consequently, any obviousness rejection posited in view of the Yuyama et al. '883 reference would be expected to fall short in a number of different ways, including at least the following: all claim limitations not being taught, rejection being based only on similarity of inventive concept or idea, suggestion to modify being based on hindsight in view of applicant's teaching, ignoring new principles of operation utilized by Applicant, invention solved a different problem than reference, "plain meaning" of recited elements being ignored, no need of element within references, unsuggested combination, no motivation or incentive to propose combination, and not consideration applicant's invention as a whole. Any of the above being sufficient in and of itself to overcome the obviousness rejection.

It is believed that the new claims added by amendment to this application substantively contain the limitation found in Claim 1, wherein they too would not be a proper subject of an obviousness rejection based on the reference.

Therefore, Claims 1 - 8 in the application, along with the new claims of this amendment are not obvious in view of the cited reference and are patentable.

6. Amendment of Claims 1, 3, 5-6.

Claim 1. This independent claims has been amended to increase clarity. Specifically, the phrase "or equivalent" and "may" have been removed/changed to more definitively recite aspects of the invention according to recent USPTO practice. The "scheduled series of doses" as already described in the claim, such as in the clause describing the interface: "a dosing schedule is specified into which supplements and/or medications (MS) from said pill repository are entered to create a description of a series

of doses which is communicated to said packetizing system for packaging said series of doses". has been added to the preamble and to the description of the packeting system operation.

Therefore, this claim amendment is self supporting and does not alter the scope of the invention.

Claim 3. This dependent claim was amended to more clearly recite the relationship between the labeling and the series of packetized doses, wherein the labels are printed on or configured for attachment to the dose packets. Support for the amendment being found in the specification, such as at page 6, lines 19-21; and page 9 lines 19-23:

> *"Once all MS is collected in association with the individualized doses of the order, the DCA is received within a packetizing station which preferably verifies the MS of the individualized doses once again prior to packaging and labeling each of the doses within the order. The orders are then packaged and shipped to the consumers, or institutions."*

Claim 5. This dependent claim was amended to improve accuracy and in accord with present practice, wherein "adapted to" was replaced with "configured for" and "being" replaced with "to be" more accurate in view of the order of steps recited in the specification.

None of the above amendments have been made for the purpose of overcoming any ground for rejection or addressing any cited reference. Nor do any of the amendments made narrow the scope of claims coverage.

Claim 6. This dependent claim was amended to correct an informality and

correct claim consistency wherein "interaction/contraindication" was replaced with "interaction and contraindication" as later stated in the claim.

7. Addition of Claims 36 - 62.

The following claims are drawn to the invention of Group I, and directed to Claim 1, or an independent claim which is otherwise based on Claim 1. Applicant respectfully requests entry and proper consideration of the following independent claims and dependent claims.

Claim 36. This claim depends from Claim 1, and recites with particularity what is being referred to as pills within the specification, specifically "conventional pills, as well capsules, caplets, gel caps, and/or lozenges". Support for which is found in the specification, such at page 6, line 23 through page 7 line 5:

> *"The term medications and supplements (MS), as used herein, comprises any variety of medical and/or health related solid, or semisolid pill, for instance, conventional pills, capsules, caplets, gel caps, and lozenges. The abbreviation "MS" used herein is inclusive of new pill packaging forms as well, since solid pill forms constantly evolve and their use within the system would be obvious."*

Claim 37. This claim depends from Claim 1 and recites the packetizing of doses from said dose schedule into a "time sequential series of dose packets for a single recipient or patient, or multiple recipients or patients". Which is based on original claim 13, 20, 25, and recited in the specification such as at page 17, lines 15-20:

"A set of packets 30 for the consumer 12, is shown comprising a series of packets 32a through 32z. It will be appreciated that although it is preferable to separately retain each of the doses within individual packets which are joined to one another in a given order such as date sequential for a single patient, or by patient number (for multiple patients within an institutional setting);..."

and page 6, lines 19-21:

"Preferably, the packets are marked, or labeled, with a textual and/or graphic indicia which preferably contains the patient's name and the scheduled date and time at which the MS dose is to be utilized."

and page 11, lines 1-2:

"Another object of the invention is to provide MS as dose packets that are labeled for the date and time they are to be taken."

Claim 38. This claim depends from Claim 1 and recites packetizing the individualized doses into sealed single dose packages. Support for which is found throughout the specification, and figures (FIG. 2, 3, 4A, 23, 24), such as at page 19, lines 10 -11:

"FIG. 2 depicts a set 30 of individualized custom doses 30 exemplified as being contained within sealed glassine packets."

Claim 39. This claims depends from Claim 1 and recites an aspect of the packetizing system which allows for the efficient producing of the individualized sequence of dose packets. This claim was based on an aspect within original

independent Claim 11, and which shown in the figures (FIG. 18 - 21) and in the specification, such at page 48, lines 4 -17.

Claim 40. This claims depends from Claim 3 and recites that doses are labeled with a recipient identifier and the time that the specific individualized dose is to be taken. The elements being originally claimed in dependent Claim 13, and found throughout the specification including FIG. 2 and 3.

Claim 41. This claims depends from Claim 7, and recites the purchase transaction with greater particularity. aspect of the packetizing system which allows for the efficient producing of the individualized sequence of dose packets. Portions of the claim were recited in original claims 33, 34 and in the specification, such at page 30, lines 7 - 18; page 22, line 17 through page 8, line 7; and page 32, lines 14 - 20.

Claim 42. This is an independent claim based on Claim 1, but which frames the claim as a computer with programming.

Claim 43. This is a dependent claim which depends from Claim 42, and recites material contained in original claims 2 and 3.

Claim 44. This is a dependent claim which depends from Claim 42, and recites material contained in original claim 4, while also mentioning the use by individual and institutional buyers, such as described in the specification at page 23, lines 13 - 16:

> *"It will be appreciated that the "consumer" may be an individual consumer purchasing medications and supplements for their own use, or an institutional buyer, ordering MS for those patient under their care."*

Claim 45. This is a dependent claim which depends from Claim 42, and recites material contained in original claim 5.

Claim 46. This is a dependent claim which depends from Claim 42, and recites material contained in original claim 6.

Claim 47. This is a dependent claim which depends from Claim 42, and recites material contained in original claim 7, along with the material of new dependent Claim 41, framed to follow with Claim 42. It also specifies "said scheduled series of doses spanning a specified interval", which is shown in the figures and recited in the specification, for example 124 in FIG. 6, page 24, lines 17-20; and page 37, line 19 through page 38, line 2.

Claim 48. This is a dependent claim which depends from Claim 42, and recites material contained in original claim 8.

Claim 49. This is a dependent claim which depends from Claim 42, and recites material partially contained in original claim 8, and recited within the two case scenarios of individual buyers and institutional buyers.

Claim 50, 51. These are dependent claims which depends from Claim 42, and recite material contained in new Claim 37, which has been split here for the single and multiple patient cases. These also include the "selected time span range" recitation within new Claim 47.

Claim 52. This is a dependent claim which depends from Claim 51 which describes a method of organizing dose packets from said dose schedule. This aspect is describe for the institutional ordering and is found in the drawings as 204 of FIG. 8 and in specification, such as at page 30 line 21 through page 31 line 3.

Claim 53. This is a dependent claim which depends from Claim 42 which describes the ability of the system to maintain the dosing schedule for future access and for automatically dispensing and packetizing another scheduled series of doses in response to said dosing schedule. These aspects are shown in the figures, see 122 "Automatic ordering" within FIG. 6, and described numerously in the specification, such as page 5, lines 20-21 (the first line of summary):

The present invention is a system and a method for providing persons with individualized (custom) doses of their recurrent supplements and medications.

page 10, lines 5 - 9:

"The temporal dosing system of the present invention saves ordering and other consumer-related information for subsequent use, wherein the consumer can elect to place a recurrent order in which the selected doses are generated in a subsequent order without the need to place a new order. For example, the consumer may elect to order their supplements monthly, but want them sent automatically by a given date."

Claim 54. A dependent claim which depends from claim 42, wherein it is recited that said computer can be comprised of "multiple distributed computers interconnected by a communication link", as a further clarification of what "a computer" constitutes insofar as defined in the application, see FIG. 1, and FIG. 16 (which is diagram of interconnected computer resources) and which described at various places through the specification, such at page 45 lines 9-11:

"FIG. 16 is an embodiment which exemplifies computational resources 570 of the fulfillment portion of the temporal dosing system which is shown in a hierarchical block diagram."

Claim 55. An independent claim which is based on independent claim 42, but including limitations from the dependent claims and language orienting it toward the individual buyer. Specifically original Claim 35 describing packaging and shipping to the consumer is included, and Claim 50 reciting the time sequential order for a single recipient. The aspects of Claim 38 are included describing packetizing said doses within sealed single dose packets. The printing of user identifier and time to take the packet is included within the claim from new claim 40.

Claim 56. A dependent claim which depends from independent claim 55, and recites that the pills comprise conventional pills, capsules, caplets, gel caps, and/or lozenges, as described for new claim 36.

Claim 57. A dependent claim which depends from independent claim 55, and recites that the interface is a web site hosted on the internet, as described in new claim 44.

Claim 58. A dependent claim which depends from independent claim 55, and recites receiving authorization from the physician of the user, as described in new claim 45.

Claim 59. A dependent claim which depends from independent claim 55, and recites interaction and contraindication checking, as described in new claim 46.

Claim 60. An independent claim which is based on independent claim 42, but including limitation from the dependent claims and language orienting to use by the institutional buyer. Specifically claims 50 - 52 which are restated as an organizing step performed by the programming when a multiple recipient order is processed.

Claim 61. A dependent claim which depends from independent claim 60, and recites that the pills comprise conventional pills, capsules, caplets, gel caps, and/or lozenges, as described for new claim 36.

Claim 62. A dependent claim which depends from independent claim 60, and recites interaction and contraindication checking, as described in new claim 46.

8. Fees for Additional Claims.

No additional claims fees are necessary. The applicant canceled claims 9-35 (17 total claims), including independent claims (3 independents) which were withdrawn in response to a restriction requirement. Applicant has added back 17 total claims including 3 independents. Therein the total number of claims remains with 36 total claims and 4 independent claims.

9. Extension of time under 37 CFR 1.136(a).

Applicant has included herein a petition for an extension of time for a two (2) month extension as described in 37 CFR 1.136(a); an appropriate fee of **$210** is enclosed.

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10. Conclusion.

The patentability of the claims has been demonstrated and each of the presently pending claims in the application are believed to be in immediate condition for allowance.

The Applicant respectfully requests a response/interview (email/phone) with the Examiner to clarify any issues that arise upon examination on the merits of the present application, if an allowance of all claims does not appear forthcoming.

Applicant/inventor Rodger Rast can be reached Tuesdays and Thursdays at his home office at 916-631-9043 between 8 A.M. - 8 P.M. Pacific Standard Time.

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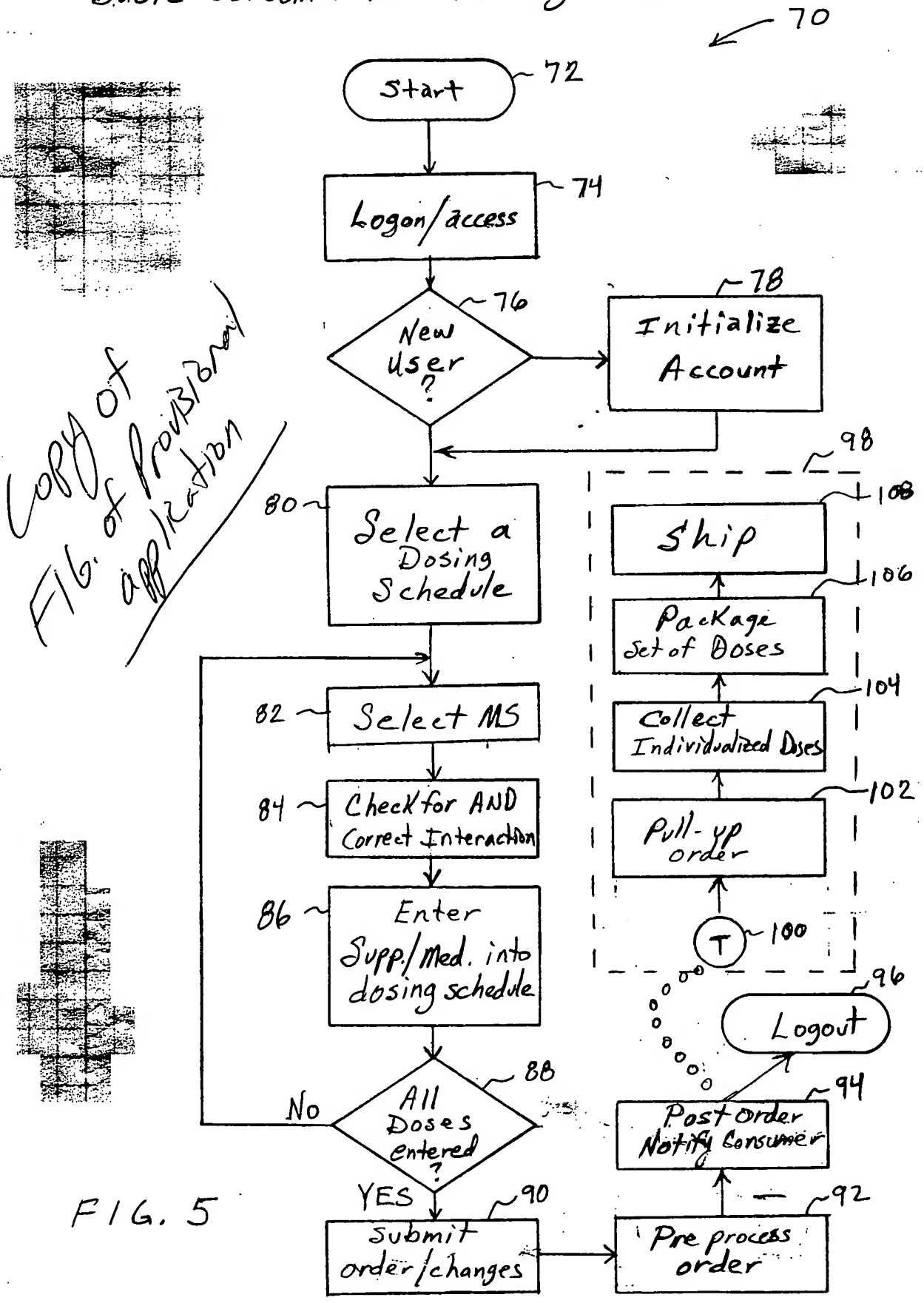
Basic Consumer Dose Delivery Process



Copy of Fig. of Provisional application

FIG. 5